REMARKS

Claims 1-59 will be pending upon entry of this Amendment C and Response After RCE. Claim 1 has been amended to correct typographical errors and to require the moisturizing and lubricating composition to further comprise from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent. Support for this amendment can be found in originally filed dependent claim 15. Claims 31-59 have been withdrawn as directed to a non-elected invention. Applicants reserve the right to file divisional applications directed to the non-elected claims.

Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-14 and 25-30 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682).

Claim 1, as amended herein, is directed to a tissue product comprising a tissue paper and a moisturizing and lubricating composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent, and from about 1% (by weight) to about 40% (by weight) of a

compatibilizing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% (by weight) of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Klofta, et al. disclose an anhydrous lotion composition for killing viruses and bacteria in addition to imparting a soft, lubricious, lotion-like feel when applied to tissue paper. The lotion composition comprises at least one antimicrobial selected from an antiviral, antibacterial, and mixtures thereof; at least one hydrophilic solvent; at least one skin conditioning agent; and at least one hydrophilic surfactant. When used in the lotion formulation, the antiviral is present in the lotion composition in an amount of from about 1% (by weight) to about 60% (by weight) and the antibacterial is present in an amount of from about 0.1% (by weight) to about 6% (by weight). Hydrophilic solvents can include glycol type solvents such as polyethylene glycols, glycerin, ethylene glycol, propylene glycol, polypropylene glycol, ethanol, isopropanol, hexylene glycol, and mixtures thereof and are present in the lotion composition in an amount of from about 5% (by weight) to about 60% (by weight).[1] Hydrophilic surfactants such as ethoxylated alcohols are present in the lotion formulation in an amount of from about 0.1% (by weight) to about 60% (by weight). Skin conditioning agents include petroleum-based agents such as mineral oil and petrolatum; fatty acid ester type agents, fatty

[1] U.S. 6,238,682 at column 17, lines 41-42.

alcohol type agents, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures thereof and are present in the lotion composition in an amount of from about 0.1% (by weight) to about 60% (by weight).[2] Typically, the skin conditioning agents have either a plastic or fluid consistency at 20°C (i.e., ambient temperatures).[3] As the skin conditioning agents have a plastic or fluid consistency at 20°C, they tend to flow or migrate on the surface of the tissue product. The lotion composition can further optionally include an immobilizing agent such as C_{12}-C_{22} fatty alcohols and C_{12}-C_{22} fatty acids in amounts of from about 5% (by weight lotion formulation) to about 60% (by weight lotion formulation).[4]

Significantly, Klofta, et al. fail to disclose from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent in their lotion formulation.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some modifications

[2] *Id.* at column 19, lines 23-26.
[3] *Id.* at column 17, lines 50-52.
[4] *Id.* at column 22, lines 51-55.

and/or combinations would have been obvious where others would not.[5] The Office has clearly failed to meet its burden under number (1) and/or (2) above, as the cited reference does not teach or suggest all of the claimed limitations and there is no apparent reason to modify the reference to arrive at each and every limitation of Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, as noted above, Klofta, et al. fail to teach or suggest including in amount of from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent in their lotion formulation. Specifically, in addition to the emollient, humectant, immobilizing agent, and compatibilizing agent, the composition of claim 1 includes a skin barrier enhancing agent, such as a fat or oil, to enhance the barrier function of the stratum corneum layer of the skin or mucous membrane. As such, this is a significant aspect of Applicants' invention.

Moreover, the common sense of one ordinarily skilled in the art would not have provided a reason to modify the Klofta, et al. reference to arrive at Applicant’s composition of claim 1. Specifically, as recognized by the Supreme Court in KSR International Co. v. Teleflex, Inc., while an obviousness determination is not a rigid formula, the TSM (teaching, suggestion, motivation) test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in

[5] Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May 9, 2007) *See also* KSR Int'l Co. v. Teleflex, Inc., et al. 550 US____, 2007 WL 1237837 at 12 (2007).

the art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known [elements] according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does."[6] More particularly, a court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions.[7] If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability. For example, in KSR, the patented invention was directed towards an improved adjustable vehicle pedal assembly, and, as has long been held in the Federal Circuit, mechanical arts are predictable.[8] Recognizing that mechanical devices such as adjustable vehicle pedals and sensors can be predictably modified and combined by one skilled in the art, the Court invalidated the patent as obvious.[9]

By contrast, areas of chemistry, such as in the instant case of Applicant's compositions, have been held inherently

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[6] *Id.* at 5.
[7] *Id.*
[8] *See* MPEP §2164.03 (*citing* In re Vickers, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); In re Cook, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971)); *See also,* In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991).
[9] KSR Int'l Co. v. Teleflex, Inc., et al. 550 US____, 2007 WL 1237837 at 17 (2007). Specifically, the Court held that there was convincing evidence that mounting a modular sensor on a fixed pivot point of a pedal was a design step well within the foreseeable grasp of a person or ordinary skill in the relevant art and, as such, the claimed adjustable pedal assembly of claim 4 was obvious.

unpredictable. Specifically, as stated in In re Marzocchi,[10] "in the field of chemistry generally, there may be times when the well-known *unpredictability* (emphasis added) of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of [generalized] broad statements." That is, chemical reactions are, by their nature, unpredictable and, as such, generalized or broadly disclosed elements cannot necessarily be predictably modified.

As noted above, Klofta, et al. fail to teach that their lotion formulation can include an amount of from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent. And, as chemical reactions are inherently unpredictable, it cannot be stated that one skilled in the art, reading the Klofta, et al. reference, could simply add a skin barrier enhancing agent to the formulation of Klofta, et al. and arrive at the compositions of Applicants' claim 1. That is, it is not foreseeable or predictable that one skilled in the art could simply combine additional components into the Klofta, et al. formulation to arrive at the specific compositions, having the specific desirable physical properties, of Applicant's claim 1.

And further, since the Klofta, et al. reference, as noted above, fails to provide a reason why one skilled in the art would choose to include from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent in their lotion formulation, it would not be predictable for one skilled in the art to modify the lotion formulation to arrive at a composition including from about 0.1% (by weight) to about 30% (by weight)

[10] 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971).

of a skin barrier enhancing agent, as required in Applicants' claim 1.

Additionally, Applicants maintain that Klofta, et al. also fail to teach or suggest the desired ranges of emollient, humectant, immobilizing, and compatibilizing agent in their lotion composition. The Office states that although Klofta, et al. fail to teach all the percentages recited in instant claim 1, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results. Applicants respectfully disagree that the desired amounts are a result of routine experimentation.

As noted above, the compositions of the present disclosure comprise a certain percentage of components, such as 30% (by weight) to about 90% (by weight) immobilizing agents to ensure that at least 50% (by weight) of the components are solid at room temperature. Immobilizing agents, as noted above, are essential in providing a network that is capable of supporting the liquid components within it and, therefore, preventing their migration through the substrate. Significantly, the Klofta, et al. reference discloses that the immobilizing agent is merely an **optional** ingredient in their lotion formulations. Furthermore, when the immobilizing agents are present, Klofta, et al. disclose using significantly lower amounts of immobilizing agent. These lower amounts of immobilizing agent in Klofta, et al., particularly in combination with the higher amounts of humectant- and emollient-like skin conditioning agents, will not

provide compositions having the necessary consistency to prevent migration of the composition into the substrates of the tissue product.

Furthermore, as noted above, as chemical reactions and compositions are inherently unpredictable, it is not foreseeable or predictable that one skilled in the art could modify the amounts of the components in the Klofta, et al. formulation to arrive at the specific compositions, having the specific physical properties, of Applicant's claim 1.

As Klofta, et al. fail to disclose a lotion formulation including from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent as required in amended claim 1, and further, there is no apparent reason for one skilled in the art to modify the compositions of Klofta, et al. to arrive at the compositions of claim 1, claim 1 is patentable over the Klofta, et al. reference.

Claims 2-14 and 25-30 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

2. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1 and 15-22 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Krzysik, et al. (U.S. Patent No. 6,440,437).

Claim 1 is discussed above.

Klofta, et al. is discussed above. Significantly, as discussed above, Klofta, et al. fail to disclose that their lotion formulation includes from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent as required in claim 1.

Recognizing that Klofta, et al. fail to make such a disclosure, the Office cites Krzysik, et al. for combination with the Klofta, et al. reference. Specifically, the Office states that it would have been obvious to a person having ordinary skill in the art to combine the cited references as there would be an improved beneficial effect of a soft and lubricious feel and a better maintained skin barrier function.

Krzysik, et al. disclose a skin health enhancing soft wet wipe comprising an oil-in-water emulsion composition. The oil-in-water composition comprises a natural fat or oil, sterol or sterol derivative, humectant, emulsifying surfactant, and water. Specifically, in one exemplary embodiment, the oil-in-water composition comprises from about 0.1 to about 30 weight percent of natural fats or oils, from about 0.1 to about 10 weight percent of a sterol or sterol derivative, from about 0.1 to about 99.5 weight percent of an humectant, and from about 0.5 to about 20 weight percent of an emulsifying surfactant having an HLB range of about 7 to about 18, from about 45 to about 99.5 weight percent of water and the pH of the emulsion adjusted to a pH of about 4 to about 7.[11]

As noted in M.P.E.P. §2142, in establishing obviousness, the Office must show references that teach all of the claimed

[11] U.S. 6,440,437 at column 3, lines 21-29.

limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests a reason for the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). As noted above, while this test is not a rigid formula, it does provide helpful insight as it can be important to identify a reason that would have prompted a person of ordinary skill in the art to modify the elements as the new invention does. A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the formulations of the Klofta, et al. and the Krzysik, et al. references would not have been made.[12]

[12] M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al. and Krzysik, et al. references to arrive at Applicants' amended claim 1. Specifically, a close reading of the Krzysik, et al. reference actually teaches away from the combination of the Klofta, et al. and Krzysik, et al. references.

Specifically, as disclosed in Klofta, et al., it is desirable for the lotion compositions to be anhydrous lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.[13] As noted above, however, the Krzysik, et al. composition comprises from about 45% to about 99.5% by weight water. The water contained in the Krzysik, et al. composition may be a mixture of water and alcohol. The amount of alcohol in the water is up to about 70 weight percent of the water and alcohol solution.[14] Even if alcohol is present in 70 weight percent of the water and alcohol solution, however, the compositions of Krzysik, et al. comprise at least about 13.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Krzysik, et al. reference, which are desirably incorporated into compositions having at least 13.5% by weight water with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water. As such, there is no motivation

[13] U.S. 6,238,682 at column 10, lines 51-57.
[14] U.S. 6,440,437 at column 3, lines 61-67.

or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

Claims 15-22 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

3. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1 and 23-24 under 35 U.S.C. §103(a) as being unpatentable over Klofta, et al. (U.S. Patent No. 6,238,682) in view of Bowser, et al. (U.S. Patent No. 5,342,976).

Claim 1 is discussed above.

Klofta, et al. is discussed above. Significantly, as discussed above, Klofta, et al. fail to disclose from about 0.1% (by weight) to about 30% (by weight) of a skin barrier enhancing agent in their lotion formulation as required in claim 1.

Bowser, et al. disclose a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain ω-hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the

skin in an appropriate dilution. One suitable vehicle is water. In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

As noted above, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the formulations of the Klofta, et al. and the Bowser, et al. references would not have been made.[15]

[15] M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art, to combine the Klofta, et al. and Bowser, et al. references to arrive at Applicants' amended claim 1. Specifically, similar to the Krzysik, et al. reference discussed above, a close reading of the Bowser, et al. reference actually teaches away from the combination of the Klofta, et al. and Bowser, et al. references.

Specifically, as noted above, it is desirable for the lotion compositions of Klofta, et al. to be anhydrous lotions, typically comprising less than about 5% (by weight) water, preferably about 1.0% (by weight) or less water, more preferably about 0.5% (by weight) or less water, and most preferably about 0.1% (by weight) or less water.[16] As noted above, however, the Bowser, et al. composition can comprise from about 15% to 99.9999% by weight water and, preferably from 50% to 99.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having at least 15% by weight water and, more preferably at least 50% by weight water, with the lotion compositions of Klofta, et al., which desirably comprise less than 5% (by weight) water. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

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gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

Claims 23-24 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

5. Double Patenting Rejections

Claims 1-30 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-61 of copending Application No. 10/659,969.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,969 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.

[16] U.S. 6,238,682 at column 10, lines 51-57.

CONCLUSION

In light of the foregoing, applicants request withdrawal of the rejections of claims 1-30 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

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